Department of Veterans' Affairs
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, MO 65201

HPM 589A4-339
November 15, 2004
Issued by: Research

Conflict of Interest in Research

1. **PURPOSE**: To establish policy and procedures regarding Conflict of Interest (COI) in research which will enable investigators (i.e., principal investigators, co-principal investigators, investigators, and collaborators with five percent [5%] or more effort) and research committee members (i.e., Research and Development [R&D], Institutional Review Board [IRB], Subcommittee for Animal Studies [SAS], and Subcommittee for Research Safety [SRS]) to comply with applicable VA and other federal and state regulations regarding conflicts of interest in research.

2. **DEFINITION**:

a. A conflict of interest is defined as any financial arrangement, situation, or action that exerts, or is perceived to exert, inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Financial conflict of interest may include, but is not limited to, the following:

(1) Salary or other payments for services (e.g., consulting fees or honoraria);

(2) Compensation to investigator if the amount of the compensation could be affected by study outcome;

(3) Equity interests (stocks, stock options or other ownership interests); and

(4) Intellectual property rights (e.g., patents, copyrights and royalty from such rights).

b. Significant financial conflict of interest does **not** include:

(1) Salary, royalties, or other remuneration from the applicant's home institution;

(2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(3) Income from service on advisory committees or review panels for public or nonprofit entities;

(4) An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests:

(a) does **not** exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and

(b) does **not** represent more than 5% of ownership interest in any single entity; or

(5) Salary, royalties, or other payments that when aggregated for the investigator, spouse, and dependents over twelve (12) months, are **not** expected to exceed $10,000.

3. **SCOPE**: Investigators must comply with all laws, regulations, and policies of applicable Federal Agencies, including VA, and any applicable state regulations pertaining to conflict of interest in research. All research proposals submitted to the Harry S. Truman Memorial Veterans' Hospital (HSTMVH) for review must contain a Conflict of Interest Statement (VA Form 1313-9) identifying conflicts of interest (Appendix A). This requirement applies to all research activities conducted completely or partially in VA facilities, conducted in approved off-site locations and/or facilities, and/or conducted by VA investigators while on official VA duty time, whether funded by VA or by other sources, or unfunded.

4. **RESPONSIBILITIES**:

a. Hospital Director:

(1) The Hospital Director is the Institutional Official responsible for the Research and Development (R&D) program, including resolution of issues related to COI in research.

(2) The Hospital Director will designate a COI Administrator to oversee the day-to-day activities related to the COI in the research program.

(3) The Hospital Director will regularly review findings by the COI Administrator, the IRB, and the R&D Committee regarding identified COI. The Hospital Director may add stipulations or requirements identified by the COI Administrator and/or recommended by applicable committees. In situations in which a conflict of interest cannot be resolved, the Hospital Director will make the final binding decision regarding the COI and how it should be managed.

b. Conflict of Interest Administrator:

(1) The Associate Chief of Staff for Research & Development (ACOS/R&D) is the designated Conflict of Interest Administrator. The COI Administrator is responsible for reviewing financial disclosure statements from each investigator who is planning to participate in the HSTMVH research program. These financial disclosure statements will be reviewed, and the findings will be made available to the R&D Committee.

(2) For research that is carried out through collaboration, the ACOS/R&D will ensure that all investigators comply with the provisions of VHA Handbook 1200.13 and all other policies, procedures, and regulations related to COI.

c. Institutional Review Board (IRB): The Research & Development program at the HSTMVH, through a Memorandum of Understanding, utilizes the University of Missouri-Columbia Health Sciences IRB. The administrative liaison from the HSTMVH to the IRB is the Human Research Compliance Officer (HRCO), who is responsible for monitoring IRB discussion of conflict of interest and co-signing VA Form 1313-9.

d. R&D Committee: The R&D Committee will review the actions taken by the IRB. They may approve the IRB's actions, and may add stipulations or changes to the proposal, but the R&D Committee may not disallow any of the IRB's stipulations or required changes

regarding the COI. The R&D Committee also is responsible for issues involving COI for studies not involving human subjects. For these studies, the Committee will determine what actions should be taken by the institution or the investigator to manage, reduce, or eliminate COI.

e. Investigator: The investigator is responsible for disclosing any COI. This disclosure must be documented through the use of the COI Statement, VA Form 1313-9, available on the HSTMVH Research web site. If a COI develops after approval of the protocol, the conflict must be immediately reported. Conflicts of interest involving the investigator's spouse or dependent children that would reasonably appear to affect the research also must be reported. Investigators should consider the potential effect that a financial relationship of any kind might have on a clinical trial, including interactions with research subjects.

5. **PROCEDURES**: Conflicts of Interest will be evaluated and managed as follows:

a. Compliance with HSTMVH policies related to COI will be assessed through periodic audits conducted by the HRCO.

b. The COI policy requires disclosure of any potential COI to appropriate officials or committees.

c. The Common Rule prohibits IRB and R&D members and/or staff who have a COI from participating in the discussion (or voting) in initial or continuing reviews except to answer questions. Accordingly, IRB and R&D members are required to declare situations in which a COI, or a potential or CO, exists. Members of the IRB and/or R&D Committee who have a conflict of interest must recuse themselves from review of proposals for which the conflict exists.

d. Investigators must submit the Conflict of Interest Statement (VA Form 1313-9) as a component of the research application.

e. The COI Administrator will review the financial disclosure statement and determine if there will be a negative impact on the research.

f. The IRB (with monitoring by the HRCO) will review COI issues when reviewing the protocol. The IRB must consider any matter that raises the possibility of coercion or undue influence in the consent process. If a COI is identified, the IRB will assess the necessary actions to minimize risks to subjects.

g. THE COI Administrator will present a review of COI issues to the R&D Committee in the context of protocol deliberations.

h. The IRB and R&D Committee may initiate remedies to manage or eliminate conflict of interest as follows: (a) modify the protocol, (b) change the consent to reflect the COI, (c) disclose significant financial interests; and/or (d) monitor the research by independent reviewers.

i. When a significant COI exists and is not remedied by the process described above, a non-biased third party may be authorized to obtain informed consent if a potential or actual COI could influence the tone, presentation, or type of information discussed during the consent process. Independent monitoring may be necessary in this instance.

j. The Hospital Director will be informed of any inability to resolve significant COI or if

an investigator fails to comply with the COI policy. The Hospital Director may impose remedies and/or restrictions including, but not limited to, the following: (a) termination of the research study; (b) removal of the investigator from the research study; (c) revocation of the privilege to conduct research; or (d) sanctions, which may include prohibition from submitting proposals to the IRB and/or R&D Committees.

6. **REFERENCES**:

a. VHA HANDBOOK 1200.13 *Department of Veterans Affairs, Veteran's Health Administration, Washington DC*

b. Managing Conflicts of Interest in Human Subject's Research, *Katherine A Chaurette and Christopher M. Jedry*

c. U.S General Accounting Office*, HHS Direction Needed to Address Financial Conflicts of Interest (November 2001)*

d. Association of American Medical Colleges, *Protecting Subjects, Preserving Trust, Promoting Progress--Policy and Guidelines for the Oversight of Financial Interests in Human Subjects Research*

e. *Federal Register/Vol. 68, No. 61/Monday, March 31, 2003/Notices*

7. **FOLLOW-UP RESPONSIBILITY.** The ACOS for Research and Development (Mail Code 151) is responsible for the follow-up of this HPM.

8. **RESCISSION**: None.

APPROVED:

GARY L. CAMPBELL
Director

Appendix A
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Veterans Administration

CONFLICT OF INTEREST STATEMENT

This document must be completed, signed and submitted by each principal investigator, co-principal investigator, investigator and collaborator who plans to devote 5 percent or more effort to the proposed project. The information will be used only to review the proposed research project to which it applies. This completed and signed document must accompany the proposal to which it applies or the proposal will not be considered for further review.

NOTE: If any questions below are answered in the affirmative, the conflict must be managed with the assistance of the VA Regional Counsel. See the document "Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208" in 5 CFR part 2640.

TITLE OF RESEARCH PROPOSAL:

NAME: STUDY NO.

ROLE (check one) ☐ Principal Investigator ☐ Co-Principal Investigator

☐ Research Coordinator ☐ Collaborator

Please check your answer:	YES	NO
1. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner **receive salary or other compensation** (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a business or other source related to the research proposal that in aggregate has in the prior year exceeded $10,000 and/or is expected to exceed $10,000 in the next 12 months?	☐	☐
If Yes, explain source, value and reason for compensation:		
2. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner **own any patents** that are related to the research project proposal? If Yes, please provide additional information below:	☐	☐
Patent number: Date of Patent:		
Title of Patent:		
Have any active or pending license agreements been issued? (If Yes, attach a copy of each license.)	☐	☐

	If Yes, describe the period covered by each license and the projected royalty by year.		
3.	Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner **own any <u>provisional</u> patents** that are related to the research project proposal? If Yes, please provide additional information below:	**YES** ☐	**NO** ☐
	Patent Application Number: Date Filed:		
	Title of Provisional Patent:		
	Have any active or pending license agreements been issued? (If Yes, attach a copy of each license.)	☐	☐
	If Yes, describe the period covered by each license and the projected royalty by year.		
4.	Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own or **have any equity interests** by way of stock ownership or stock options in a non-publicly-traded company that may or may not own a patent that is related to the research project proposal?	☐	☐
	If Yes, what is the value of the stock/stock options?		
	Does this value represent more than a 5% ownership of the company?	☐	☐
5.	Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a publicly-traded company that may or may not own a patent that is related to the research project proposal and is valued at more than $10,000 (or value is projected to exceed $10,000 in the next 12 months)?	☐	☐
	If Yes, what is the value of the stock/stock options?		

Does this value represent more than a 5% ownership of the company?	☐	☐

6. Please describe any of your VA duties that involve management of research project or contracts other than those on which you are a principal investigator, co-principal investigator or investigator. This includes oversight, approval, advising, recommending, or initiating actions on research related projects. Indicate if None.

I certify that, to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete and made in good faith. I understand that false or fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

Signature of Investigator	Date Signed
Signature of Investigator's Supervisor	Date Signed
Signature of Associate Chief of Staff for Research	Date signed

Certification of Review by Conflict of Interest Administrator or Committee

This Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

A financial conflict of interest: ☐ <u>has</u> ☐ <u>has not</u> been identified for this investigator on this research protocol. If a conflict of interest has been identified, the following actions are recommended:

(Signature of Conflict of Interest Administrator or Committee Chair) Date

Certification of Review by Institutional Review Board (IRB):

☐ **Review by IRB is not applicable to this protocol.**
(check if applicable)

(Signature of IRB Administrator) Date

This Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

A financial conflict of interest: ☐ has ☐ has not been identified for this investigator on this research protocol.

Concur with recommendation of COI Administrator/Committee: ☐ Yes ☐ No

Any additional recommendations are addressed by letter from the IRB chair to the Investigator.

(Signature of IRB Administrator) Date

Certification of Review by Research and Development Committee

This Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

A financial conflict of interest: ☐ has ☐ has not been identified for this investigator on this research protocol.
Recommendations:

Concur with recommendation of COI Administrator/Committee: ☐ Yes ☐ No

Concur with recommendation of IRB: ☐ Yes ☐ No

Any additional recommendations are addressed by letter from the IRB chair to the

Investigator

(Signature of R&D Committee Chair) Date